

109TH CONGRESS
1ST SESSION

S. 518

To provide for the establishment of a controlled substance monitoring program
in each State.

IN THE SENATE OF THE UNITED STATES

MARCH 3, 2005

Mr. SESSIONS (for himself, Mr. DURBIN, Mr. KENNEDY, and Mr. DODD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide for the establishment of a controlled substance
monitoring program in each State.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “National All Schedules
5 Prescription Electronic Reporting Act of 2005”.

6 **SEC. 2. CONTROLLED SUBSTANCE MONITORING PROGRAM.**

7 Part P of title III of the Public Health Service Act
8 (42 U.S.C. 280g et seq.) is amended by adding after sec-
9 tion 399N the following:

1 **“SEC. 3990. CONTROLLED SUBSTANCE MONITORING PRO-**
2 **GRAM.**

3 “(a) GRANTS.—

4 “(1) IN GENERAL.—Each fiscal year, the Sec-
5 retary shall award a grant to each State with an ap-
6 plication approved under this section to enable the
7 State—

8 “(A) to establish and implement a State
9 controlled substance monitoring program; or

10 “(B) to make improvements to an existing
11 State controlled substance monitoring program.

12 “(2) DETERMINATION OF AMOUNT.—

13 “(A) MINIMUM AMOUNT.—In making pay-
14 ments under a grant under paragraph (1) for
15 a fiscal year, the Secretary shall allocate to
16 each State with an application approved under
17 this section an amount that equals 0.5 percent
18 of the amount appropriated to carry out this
19 section for that fiscal year.

20 “(B) ADDITIONAL AMOUNTS.—In making
21 payments under a grant under paragraph (1)
22 for a fiscal year, the Secretary shall allocate to
23 each State with an application approved under
24 this section an additional amount which bears
25 the same ratio to the amount appropriated to
26 carry out this section for that fiscal year and

1 remaining after amounts are made available
2 under paragraph (1) as the number of phar-
3 macies of the State bears to the number of
4 pharmacies of all States with applications ap-
5 proved under this section (as determined by the
6 Secretary), except that the Secretary may ad-
7 just the amount allocated to a State under this
8 subparagraph after taking into consideration
9 the budget cost estimate for the State's con-
10 trolled substance monitoring program.

11 “(3) TERM OF CERTAIN GRANTS.—Grants
12 awarded under this section shall be for a term of 18
13 months.

14 “(b) DEVELOPMENT OF MINIMUM STANDARDS AND
15 RECOMMENDATIONS.—

16 “(1) IN GENERAL.—Not later than 30 days
17 after the date of enactment of this section, the Sec-
18 retary shall—

19 “(A) develop minimum standards for use
20 by States in submitting their proposed stand-
21 ards under clauses (ii), (v), (vi), and (vii) of
22 subsection (c)(1)(A); and

23 “(B) develop recommendations with re-
24 spect to appropriate penalties for the provision

1 or use of information in violation of applicable
 2 Federal, State, or local law or regulation.

3 “(2) REPORT.—Not later than 1 year after the
 4 date of enactment of this section, the Secretary shall
 5 report to Congress on the recommendations devel-
 6 oped under paragraph (1)(B) and the extent to
 7 which existing penalties meet, exceed, or fall short of
 8 such recommendations.

9 “(c) APPLICATION APPROVAL PROCESS.—

10 “(1) IN GENERAL.—To be eligible to receive a
 11 grant under this section, a State shall submit, and
 12 have approved in accordance with paragraph (2), an
 13 application to the Secretary at such time, in such
 14 manner, and containing such assurances and infor-
 15 mation as the Secretary may reasonably require.
 16 Each such application shall include—

17 “(A) with respect to a State that intends
 18 to use funds under the grant as provided for in
 19 subsection (a)(1)(A)—

20 “(i) a budget cost estimate for the
 21 controlled substance monitoring program
 22 to be implemented under the grant;

23 “(ii) proposed standards for security
 24 for information handling and for the data-
 25 base maintained by the State under sub-

1 section (e) generally including efforts to
2 use appropriate encryption technology or
3 other appropriate technology to protect the
4 security of such information;

5 “(iii) an agreement to adopt, to the
6 extent practicable, applicable health infor-
7 mation technology standards, as deter-
8 mined by the Secretary;

9 “(iv) proposed standards for meeting
10 the uniform electronic format requirement
11 of subsection (h);

12 “(v) proposed standards for avail-
13 ability of information and limitation on ac-
14 cess to program personnel;

15 “(vi) proposed standards for access to
16 the database, and procedures to ensure
17 database accuracy;

18 “(vii) proposed standards for the pro-
19 vision of information, including a descrip-
20 tion of the certification process to be ap-
21 plied to requests for information under
22 subsection (f);

23 “(viii) proposed penalties for the pro-
24 vision or use of information in violation of

1 applicable Federal, State, or local law or
2 regulation; and

3 “(ix) assurances of compliance with
4 all other requirements of this section; or

5 “(B) with respect to a State that intends
6 to use funds under the grant as provided for in
7 subsection (a)(1)(B)—

8 “(i) a budget cost estimate for the
9 controlled substance monitoring program
10 to be improved under the grant;

11 “(ii) a plan for ensuring that the
12 State controlled substance monitoring pro-
13 gram is in compliance with the standards
14 and penalty requirements described in
15 clauses (ii) through (viii) of subparagraph
16 (A);

17 “(iii) a plan to enable the State con-
18 trolled substance monitoring program to
19 achieve interoperability with at least one
20 other State controlled substance moni-
21 toring program, including—

22 “(I) the technical achievement of
23 information sharing between the two
24 programs;

1 “(II) measures to ensure that
2 interoperability activities carried out
3 under this subsection are in compli-
4 ance with the requirements of sub-
5 paragraph (A);

6 “(III) measures to ensure that
7 proposed standards for information
8 access will be enforced for shared in-
9 formation; and

10 “(IV) the completion of interstate
11 legal compacts necessary for such in-
12 formation sharing; and

13 “(iv) assurances of compliance with
14 all other requirements of this section or a
15 statement describing why such compliance
16 is not feasible or is contrary to the best in-
17 terests of public health in such State.

18 “(2) APPROVAL OR DISAPPROVAL.—

19 “(A) IN GENERAL.—Not later than 90
20 days after the submission by a State of an ap-
21 plication under paragraph (1), the Secretary
22 shall approve or disapprove the application, or
23 request additional information as provided
24 under subparagraph (C). The Secretary may
25 disapprove an application that contains a state-

ment described in paragraph (1)(B)(iv), or request additional information with respect to such a statement, if the Secretary determines that the approval of such application would result in the implementation of a State program that substantially fails to meet the goals and objectives of this section.

“(B) APPROVAL.—The Secretary shall approve an application submitted under paragraph (1) only if—

“(i) the plans contained in the application meet the standards developed by the Secretary under subsection (b); and

“(ii) the State demonstrates to the Secretary that the State will establish and implement or improve a controlled substance monitoring program in accordance with this section.

“(C) ADDITIONAL INFORMATION.—With respect to an application submitted by a State under paragraph (1), the Secretary may, during the 90-day period referred to in subparagraph (A), request that the State provide additional information with respect to the State program. If such a request is made after the expiration

1 of the 60-day period beginning on the date on
2 which the application is submitted, the period
3 under subparagraph (A) for approval or dis-
4 approval by the Secretary shall be extended for
5 an additional 30 days.

6 “(3) WITHDRAWAL OF AUTHORIZATION.—Ex-
7 cept to the extent that a State is excused from com-
8 pliance with a requirement or standard as a result
9 of the approval by the Secretary of a statement
10 under paragraph (1)(B)(iv) or under subsection (d),
11 if a State fails to implement or improve a controlled
12 substance monitoring program in accordance with
13 this section or fails to comply with the standards de-
14 veloped under this subsection—

15 “(A) the Secretary shall give notice of the
16 failure to the State; and

17 “(B) if the State fails to take corrective
18 action within a reasonable period of time, the
19 Secretary shall withdraw any approval of the
20 State’s application under this section.

21 “(4) VOLUNTARY DISCONTINUANCE.—A fund-
22 ing agreement for the receipt of a grant under this
23 section is that the State involved will give a reason-
24 able period of notice to the Secretary before ceasing
25 to implement or operate a controlled substance mon-

1 itoring program under this section. The Secretary
2 shall determine the period of notice that is reason-
3 able for purposes of this paragraph.

4 “(5) RETURN OF FUNDS.—If the Secretary
5 withdraws approval of a State’s application under
6 this section, or the State chooses to cease to imple-
7 ment or improve a controlled substance monitoring
8 program under this section, a funding agreement for
9 the receipt of a grant under this section is that the
10 State will return to the Secretary an amount which
11 bears the same ratio to the overall grant as the re-
12 maining time period for expending the grant funds
13 bears to the overall time period for expending the
14 grant (as specified by the Secretary at the time of
15 the grant).

16 “(d) REPORTING REQUIREMENTS.—In implementing
17 or improving a controlled substance monitoring program
18 under this section, a State shall comply, or with respect
19 to a State that applies for a grant under subsection
20 (a)(1)(B) submit to the Secretary for approval a state-
21 ment of why such compliance is not feasible or is contrary
22 to the best interests of public health in such State, with
23 the following:

24 “(1) The State shall require dispensers to re-
25 port to such State each dispensing in the State of

1 a controlled substance to an ultimate user not later
2 than 1 week after the date of such dispensing.

3 “(2) The State may exclude from the reporting
4 requirement of this subsection—

5 “(A) the direct administration of a con-
6 trolled substance to the body of an ultimate
7 user;

8 “(B) the dispensing of a controlled sub-
9 stance in a quantity limited to an amount ade-
10 quate to treat the ultimate user involved for 48
11 hours or less; or

12 “(C) the administration or dispensing of a
13 controlled substance in accordance with any
14 other exclusion identified by the Secretary for
15 purposes of this paragraph.

16 “(3) The information to be reported under this
17 subsection with respect to the dispensing of a con-
18 trolled substance shall include the following:

19 “(A) Drug Enforcement Administration
20 Registration Number of the dispenser.

21 “(B) Drug Enforcement Administration
22 Registration Number and name of the practi-
23 tioner who prescribed the drug.

24 “(C) Name, address, and telephone num-
25 ber of the ultimate user or such contact infor-

1 mation of the ultimate user as the Secretary de-
2 termines appropriate.

3 “(D) Identification of the drug by a na-
4 tional drug code number.

5 “(E) Quantity dispensed.

6 “(F) Estimated number of days for which
7 such quantity should last.

8 “(G) Number of refills ordered.

9 “(H) Whether the drug was dispensed as
10 a refill of a prescription or as a first-time re-
11 quest.

12 “(I) Date of the dispensing.

13 “(J) Date of origin of the prescription.

14 “(4) The State shall require dispensers to re-
15 port information under this section in accordance
16 with the electronic format specified by the Secretary
17 under subsection (h), except that the State may
18 waive the requirement of such format with respect to
19 an individual dispenser.

20 “(e) DATABASE.—In implementing or improving a
21 controlled substance monitoring program under this sec-
22 tion, a State shall comply with the following:

23 “(1) The State shall establish and maintain an
24 electronic database containing the information re-
25 ported to the State under subsection (d).

1 “(2) The database must be searchable by any
2 field or combination of fields.

3 “(3) The State shall include reported informa-
4 tion in the database in a manner consistent with
5 standards established by the Secretary, with appro-
6 priate safeguards for ensuring the accuracy and
7 completeness of the database.

8 “(4) The State shall take appropriate security
9 measures to protect the integrity of, and access to,
10 the database.

11 “(f) PROVISION OF INFORMATION.—

12 “(1) IN GENERAL.—Subject to subsection (g),
13 in implementing or improving a controlled substance
14 monitoring program under this section, a State may
15 provide information from the database established
16 under subsection (e) and, in the case of a request
17 under paragraph (3), summary statistics of such in-
18 formation, in response to a request by—

19 “(A) a practitioner (or the agent thereof)
20 who certifies, under the procedures determined
21 by the State, that the requested information is
22 for the purpose of providing medical or pharma-
23 ceutical treatment or evaluating the need for
24 such treatment to a bona fide current patient;

1 “(B) any local, State, or Federal law en-
2 forcement, narcotics control, licensure, discipli-
3 nary, or program authority, who certifies, under
4 the procedures determined by the State, that
5 the requested information is related to an indi-
6 vidual investigation or proceeding involving the
7 unlawful diversion or misuse of a schedule II,
8 III, or IV substance, and such information will
9 further the purpose of the investigation or as-
10 sist in the proceeding;

11 “(C) the controlled substance monitoring
12 program of another State or group of States
13 with whom the State has established an inter-
14 operability agreement;

15 “(D) any agent of the Department of
16 Health and Human Services, a State medicaid
17 program, a State health department, or the
18 Drug Enforcement Administration who certifies
19 that the requested information is necessary for
20 research to be conducted by such department,
21 program, or administration, respectively, and
22 the intended purpose of the research is related
23 to a function committed to such department,
24 program, or administration by law that is not
25 investigative in nature; or

1 “(E) an agent of the State agency or enti-
2 ty of another State that is responsible for the
3 establishment and maintenance of that State’s
4 controlled substance monitoring program, who
5 certifies that—

6 “(i) the State has an application ap-
7 proved under this section; and

8 “(ii) the requested information is for
9 the purpose of implementing the State’s
10 controlled substance monitoring program
11 under this section.

12 “(2) DRUG DIVERSION.—A State that elects to
13 exercise its authority to notify the appropriate au-
14 thorities responsible for drug diversion investigations
15 if information in the database maintained by the
16 State under subsection (e) is suggestive of an unlaw-
17 ful diversion or misuse of a controlled substance, is
18 encouraged to develop any such notification program
19 in consultation with representatives of the medical
20 community, including physicians and pharmacists or
21 other interested stakeholders.

22 “(g) LIMITATIONS.—In implementing or improving a
23 controlled substance monitoring program under this sec-
24 tion, a State—

1 “(1) shall make reasonable efforts to limit the
2 information provided pursuant to a valid request
3 under subsection (f)(1) to the minimum necessary to
4 accomplish the intended purpose of the request; and

5 “(2) shall limit information provided in re-
6 sponse to a request under subsection (f)(1)(D) to in-
7 formation provided in a form and manner that pre-
8 vents the identification of a provider or patient.

9 “(h) ELECTRONIC FORMAT.—The Secretary shall
10 specify a uniform electronic format for the reporting, shar-
11 ing, and provision of information under this section.

12 “(i) RULES OF CONSTRUCTION.—

13 “(1) FUNCTIONS OTHERWISE AUTHORIZED BY
14 LAW.—Nothing in this section shall be construed to
15 restrict the ability of any authority, including any
16 local, State, or Federal law enforcement, narcotics
17 control, licensure, disciplinary, or program authority,
18 to perform functions otherwise authorized by law.

19 “(2) NO PREEMPTION.—Nothing in this section
20 shall be construed as preempting any State law, ex-
21 cept that no such law may relieve any person of a
22 requirement otherwise applicable under this Act.

23 “(3) ADDITIONAL PRIVACY PROTECTIONS.—
24 Nothing in this section shall be construed as pre-

1 emptying any State from imposing any additional pri-
 2 vacy protections.

3 “(4) CERTAIN CONFIDENTIALITY REQUIRE-
 4 MENTS.—Nothing in this section shall be construed
 5 as superseding the confidentiality requirements of
 6 programs defined by and subject to part 2 of title
 7 42, Code of Federal Regulations.

8 “(5) NO FEDERAL PRIVATE CAUSE OF AC-
 9 TION.—Nothing in this section shall be construed to
 10 create a Federal private cause of action.

11 “(j) RELATION TO HIPAA.—Except to the extent in-
 12 consistent with this section, the provision of information
 13 pursuant to subsection (f) and the subsequent transfer of
 14 such information are subject to any requirement that
 15 would otherwise apply under the regulations promulgated
 16 pursuant to section 264(c) of the Health Insurance Port-
 17 ability and Accountability Act of 1996.

18 “(k) STUDY.—Not later than 2 years after the date
 19 of the enactment of this section, the Secretary shall—

20 “(1) complete a study that—

21 “(A) determines the progress of States in
 22 establishing and implementing controlled sub-
 23 stance monitoring programs under this section;

24 “(B) determines the progress of States in
 25 achieving interoperability between controlled

1 substance monitoring programs, including an
2 assessment of technical and legal barriers to
3 such activities and recommendations for ad-
4 dressing these barriers;

5 “(C) determines the feasibility of imple-
6 menting a real-time electronic controlled sub-
7 stance monitoring program, including the costs
8 associated with establishing such a program;
9 and

10 “(D) provides an analysis of the privacy
11 protections in place for the information re-
12 ported to the controlled substance monitoring
13 program in each State receiving a grant for the
14 establishment or operation of such program,
15 and a comparison to the privacy requirements
16 that apply to covered entities under regulations
17 promulgated pursuant to section 264(c) of the
18 Health Insurance Portability and Accountability
19 Act of 1996, along with any recommendations
20 for additional requirements for protection of
21 this information; and

22 “(E) determines the feasibility of imple-
23 menting technological alternatives to centralized
24 data storage, such as peer-to-peer file sharing
25 or data pointer systems, in controlled substance

1 monitoring programs and the potential for such
 2 alternatives to enhance the privacy and security
 3 of individually identifiable data; and

4 “(2) submit a report to the Congress on the re-
 5 sults of the study.

6 “(l) ADVISORY COUNCIL.—

7 “(1) ESTABLISHMENT.—A State may establish
 8 an advisory council to assist in the establishment,
 9 implementation, or improvement of a controlled sub-
 10 stance monitoring program under this section.

11 “(2) SENSE OF CONGRESS.—It is the sense of
 12 the Congress that, in establishing an advisory coun-
 13 cil under this subsection, a State should consult with
 14 appropriate professional boards and other interested
 15 parties.

16 “(m) DEFINITIONS.—For purposes of this section:

17 “(1) The term ‘bona fide patient’ means an in-
 18 dividual who is a patient of the dispenser or practi-
 19 tioner involved.

20 “(2) The term ‘controlled substance’ means a
 21 drug that is included in schedule II, III, or IV of
 22 section 202(c) of the Controlled Substance Act.

23 “(3) The term ‘dispense’ means to deliver a
 24 controlled substance to an ultimate user by, or pur-
 25 suant to the lawful order of, a practitioner, irrespec-

1 tive of whether the dispenser uses the Internet or
2 other means to effect such delivery.

3 “(4) The term ‘dispenser’ means a physician,
4 pharmacist, or other individual who dispenses a con-
5 trolled substance to an ultimate user.

6 “(5) The term ‘interoperability’ with respect to
7 a State controlled substance monitoring program
8 means the ability of the program to electronically
9 share reported information, including each of the re-
10 quired report components described in subsection
11 (d), with another State if the information concerns
12 either the dispensing of a controlled substance to an
13 ultimate user who resides in such other State, or the
14 dispensing of a controlled substance prescribed by a
15 practitioner whose principal place of business is lo-
16 cated in such other State.

17 “(6) The term ‘nonidentifiable information’
18 means information that is provided in a form and
19 manner that prevents the identification of a provider
20 or patient.

21 “(7) The term ‘practitioner’ means a physician,
22 dentist, veterinarian, scientific investigator, phar-
23 macy, hospital, or other person licensed, registered,
24 or otherwise permitted, by the United States or the
25 jurisdiction in which he or she practices or does re-

1 search, to distribute, dispense, conduct research with
 2 respect to, administer, or use in teaching or chemical
 3 analysis, a controlled substance in the course of pro-
 4 fessional practice or research.

5 “(8) The term ‘State’ means each of the 50
 6 States and the District of Columbia.

7 “(9) The term ‘ultimate user’ means a person
 8 who has lawfully obtained, and who possesses, a con-
 9 trolled substance for his or her own use, for the use
 10 of a member of his or her household, or for the use
 11 of an animal owned by him or her or by a member
 12 of his or her household.

13 “(n) AUTHORIZATION OF APPROPRIATIONS.—To
 14 carry out this section, there are authorized to be appro-
 15 priated—

16 “(1) \$25,000,000 for each of fiscal years 2006
 17 and 2007; and

18 “(2) \$15,000,000 for each of fiscal years 2008,
 19 2009, and 2010.”.

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